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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,356	06/28/2001	Mark A. Ritchart	END-770	3422

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/894,356	Applicant(s) RITCHART ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 - 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 - 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 20 – 38 are rejected under the judicially created doctrine of double patenting over claims 1 - 19 of U. S. Patent No. 6,280,398 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a body having a primary lumen for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a cutter having a distal cutting edge and being movable both distally and proximally relative to said body; and a band having an opening disposed therein and extending across a distal end of said tissue sampling apparatus, said opening being movable relative to said distal cutting edge in order to sever a distal end of said tissue sample.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which

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matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20 - 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 30 recite, “extending across a distal end of said tissue sampling apparatus”. Since the “tissue sampling apparatus” is only set forth in the preamble, it is the exact location of the band/severing element is unclear.

5. In reference to claim 37, it is unclear what is meant by “a desire distance”.

Although unclear, the claims have been reviewed by the examiner as best understood at this time in order to continue with the examination.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 20, 21, 23 – 25, 29 – 35 and 37 rejected under 35 U.S.C. 102(b) as being anticipated by Kothe.

In reference to claim 20, Kothe discloses a tissue sampling apparatus (Figure 2, 3) comprising: a body having a primary lumen (7) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a cutter having a distal cutting edge (33) and being movable both distally and proximally relative to said body (Col. 7, lines 42 – 45); and a band (21, 22) having an opening disposed therein and extending across a distal end of said tissue sampling apparatus, said opening being movable relative to said distal cutting edge in order to sever a distal end of said tissue sample.

In reference to claim 21, Kothe discloses the body comprising an outer sheath (9), and the cutter being disposed within the outer sheath.

In reference to claim 23, Kothe discloses an actuator disposed proximally of the body (1, 2).

In reference to claim 24, Kothe discloses a trigger for axially retracting and extending the cutter (Col. 7, lines 42 – 45).

In reference to claim 25, Kothe discloses the trigger also moving the band in order to move the opening relative to the distal cutting edge (Col. 7, lines 42 – 45).

In reference to claim 29, Kothe discloses the body lumen sized to accommodate a plurality of tissue samples (Col. 6, lines 8 – 13).

In reference to claim 30, Kothe discloses a body having a primary lumen (7) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a severing element (21, 22) having an opening disposed therein and extending across a distal end of said tissue sampling apparatus, said opening being movable relative to said distal cutting edge in order to sever a distal end of said tissue sample (Col. 6, lines 8 – 11).

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In reference to claim 31, Kothe discloses an actuator (1, 2) disposed proximally of the body.

In reference to claim 32, Kothe discloses the actuator being adapted to move the severing element in order to move the opening relative to the body (Col. 7, lines 42 – 45).

In reference to claim 33, Kothe discloses the actuator comprising a trigger (1, 2).

In reference to claim 34, Kothe discloses the actuator comprising a cam nut (3).

In reference to claim 35, Kothe discloses a cutter having a distal cutting edge (33) and being movable both distally and proximally relative to the body (Col. 7, lines 42 – 45).

In reference to claim 37, Kothe discloses a tissue sampling apparatus comprising a body lumen (7) extending therethrough and a distal end, a cutting element (33) disposed at the distal end of the body, an opening (21, 22) disposed at the distal end of the body for transverse movement across the distal end, an actuator for moving the opening, wherein the method of capturing a sample would comprise: advancing the body through a tissue portion a desire distance so that the cutting element cuts a tissue sample core as the tissue sample enters the lumen (Figure 1); and actuating the opening to move across the distal end of the body to sever a distal end of the tissue sample core (Col. 6, lines 8 – 11).

8. Claims 30 – 32 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Rishton et al.

In reference to claim 30, Rishton et al. discloses a body having a primary lumen (14) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a severing element (16) having an opening disposed therein and extending across a distal end of said tissue sampling apparatus, said opening being movable relative to said distal cutting edge in order to sever a distal end of said tissue sample (Col. 3, lines 57 – 62).

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In reference to claim 31, Rishton et al. discloses an actuator (24) disposed proximally of the body (Col. 2, lines 50 – 54).

In reference to claim 32, Rishton et al. discloses the actuator being adapted to move the severing element in order to move the opening relative to the body (Col. 3, lines 57 – 62).

In reference to claim 37, Rishton et al. discloses a method of capturing a body tissue sample using a tissue sampling apparatus comprising a body lumen (14) extending therethrough and a distal end, a cutting element (40) disposed at the distal end of the body, an opening (16) disposed at the distal end of the body for transverse movement across the distal end, an actuator for moving the opening, the method comprising: advancing the body through a tissue portion a desired distance so that the cutting element cuts a tissue sample core as the tissue sample enters the lumen (Shown in Figure 3c); and actuating the opening to move across the distal end of the body to sever a distal end of the tissue sample core (Shown in Figure 3e).

9. Claims 30 – 32, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Suzuki.

In reference to claim 30, Suzuki discloses a body having a primary lumen (11) for receiving a tissue sample, and having a distal end, a proximal end, and a longitudinal axis extending from said proximal end to said distal end; a severing element (16) having an opening disposed therein and extending across a distal end of said tissue sampling apparatus, said opening being movable relative to said distal cutting edge in order to sever a distal end of said tissue sample (Figures 4a – 4c).

In reference to claim 31, Suzuki discloses an actuator (8) disposed proximally of the body .

In reference to claim 32, Suzuki discloses the actuator being adapted to move the severing element in order to move the opening relative to the body (Col. 9, lines 35 – 46).

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In reference to claim 36, Suzuki discloses a probe fitting (10) having an aperture (20) which communicates with the primary lumen, the probe fitting being configured to receive a sensing probe for locating a lesion in a patient's body (Col. 6, lines 59 – 61).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent No. 5,267,572 to Bucalo.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
January 13, 2003



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